Appendix A

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARK LAWRENCE DEWIS,
DAVID JOHN EDWARDS, LESLEY KENDRICK,
MARIA WRIGHT, and AMIR YUSUF

Appeal 2007-1610
Application 10/955,833
Technology Center 1600

Decided: September 4, 2007

Before TONI R. SCHEINER, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 7-12. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF CASE

A problem with developing flavoring agents for fruity and herbaceous materials, such as mango flavor, is that natural plant materials do not contain a single flavoring agent, but rather contain a complex mixture of volatile components making identification of characteristic flavors very difficult.

> The volatiles of mango were analyzed by gas chromatography and a combined gas chromatograph-mass spectrometer. The volatiles were also analyzed by gas chromatography on a sulfur detector.

(Spec. 2: 21-27).

The Specification describes the discovery that ethyl 3-mercaptobutyrate – identified from mango – can be used as a flavoring and perfuming agent because of its unique flavor and odorant properties (Spec. 1-2). The claims are drawn to an ingestible composition comprising an ingestible vehicle and ethyl 3-mercaptobutyrate.

The following rejections are on appeal in this proceeding:

1) Claims 7-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Answer 13);

2) Claims 7-12 stand rejected (three separate rejections: of claims 7-12, 10-12, and 7; Answer 7, 9, and 13, respectively) under 35 U.S.C. § 112, second paragraph, as indefinite;

3) Claims 7-9 stand rejected under 35 U.S.C. § 102 as anticipated by Nielsen ("Stereoselective Reduction of Thiocarbonyl Compounds with Baker's Yeast," *Tetrahedron: Asymmetry*, 5: 403-410, 1994; referred to by the Examiner as "Nielson and Madsen") (Answer 11); and

4) Claim 7 stands rejected under 35 U.S.C. § 102(b) as anticipated by Lazier (US 2,402,639, issued Jun. 25, 1946; referred to by the Examiner as "Lazier and Signaigo") (Answer 12).

The claims in each rejection stand or fall together because separate reasons for patentability were not provided for any individual claim. We select claims 7 and 10 as representative for deciding all rejections in this appeal. *See* 37 C.F.R. § 41.37(c)(1)(vii). Claims 7 and 10 read as follows:

> 7. An ingestible composition comprising:
> (i) an ingestible vehicle; and
> (ii) an organoleptically effective amount of ethyl 3-mercaptobutyrate represented by the formula, $CH_3(SH)CHCH_2COOCH_2CH_3$ provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds.
>
> 10. The ingestible composition according to claim 7, wherein the ingestible composition is a beverage product.

CLAIM INTERPRETATION

Claim 7 is drawn to an ingestible composition comprising (i) an ingestible vehicle and (ii) ethyl 3-mercaptobutyrate "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or a part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds."

At issue in this appeal is the proper interpretation of "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds." We give the words in a claim their broadest reasonable interpretation as they would be understood by persons of skill in the art in the context of the Specification. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In this case, the phrase "naturally occurring mixture of compounds" does not appear in the Specification as originally filed. However, "naturally occurring" would be understood by persons of skill in the art to mean that it exists or is found in nature – that is, it is "a product of nature" and not "a product of human ingenuity." *Diamond v. Chakrabarty*, 447 US 303, 309, 313 (1980). Thus, we interpret a

"naturally occurring mixture of compounds" to mean a "mixture of compounds" that can be found in nature.

Ethyl 3-mercaptobutyrate was identified by the inventors as a flavorant present in the "complex mixture" of components that naturally occur in mango (Spec. 2: 21-27 and 5: 33 to 6:12). In this context, we interpret "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds" to mean that the mercaptobutyrate compound is not present in the claimed composition in the same complex form in which it would occur in nature.

We have considered, but reject, the Examiner's alternative interpretation (Answer 6-7). As we understand it, the Examiner interprets "naturally occurring mixture of compounds" phrase to mean "a mixture of naturally occurring compounds." In our opinion, the Examiner improperly interpreted "naturally occurring" to describe the compounds present in the mixture, rather than the entire mixture, itself.

The term "ingestible" as recited in claim 7 is also at issue in this proceeding. The Specification states the ethyl 3-mercaptobuyrate is useful for imparting a unique flavor to foodstuffs (Spec. 5: 33-35). It is described as useful "in a wide variety of ingestible vehicles" that include gum, confectionary products, and beverages (Spec. 8: 7-14). The term "ingestible" is also defined in the Specification to mean "all materials and compositions which are used by or which perform a function in the body" (Spec. 6: 17-21). Thus, we interpret the phrases "ingestible composition" and "ingestible vehicle" as recited in claim 7 to mean materials and compositions suitable as foods.

Written description rejection

Claims 7-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the phrase "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same as the naturally occurring mixture" of compounds is "new matter" to the application because it is not supported in the Specification as originally filed (Answer 13). "[N]owhere in the written description is language reflecting the present form of claim 7 found" (Final Office Action 9).

"The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 [65 USPQ2d 1385] (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 [19 USPQ2d 1111] (Fed. Cir. 1991)). While there is no requirement that the claimed invention be described in the identical wording that was used in the Specification, there must be sufficient disclosure to show one of skill in this art that the inventor "invented what is claimed." *See Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1235 (Fed. Cir. 2000).

According to the Specification, Appellants discovered that ethyl 3-mercaptobutyrate "possesses unexpected flavor properties and imparts a unique note to flavors" especially in foodstuffs (Spec. 5: 33-37). It is present among "[a] relatively large number of components . . . identified in

an analysis of [a solvent extract of] mango" (Spec. 5: 37 to 38). Ethyl 3-mercaptobutyrate is stated to be "present at such low concentrations in mango that it cannot be isolated from the fruit in a commercially viable way" (Spec. 6: 10-12). Instead, Appellants describe the chemical synthesis of ethyl 3-mercaptobuyrate in a "purified form, unaccompanied by substances of natural origin present in mango" (Spec. 4: 35 to 5: 2) and shows that it acts as a beneficial flavorant (Spec. 38-39 (Example 2)). Thus, Appellants' invention is the discovery that purified ethyl 3-mercaptobutyrate acts as a flavoring when introduced into foodstuffs.

The written description must be of sufficient detail to show possession of the full scope of the invention. *Pandrol USA LP v. Airboss Railway Products Inc.*, 424 F.3d 1161, 1165, 76 USPQ2d 1524, 1527 (Fed. Cir. 2005). In this case, naturally occurring mixtures are excluded from the claims, but that leaves the claim open to everything else that contains ethyl 3-mercaptobutyrate – including any composition, however modified that it is no longer naturally occurring.[1] In our opinion, such a claim scope is not justified nor drawn to what Appellants invented. The invention described in the Specification is "purified" ethyl 3-mercaptobutyrate "unaccompanied by substances of natural origin present in mango" (Spec. 4: 35 to 5: 2) as a novel flavoring or perfuming agent. This is the only invention described in the Specification. There is no detail in the Specification that shows that Appellants possessed compositions of a different scope, let alone of an intermediate scope to cover mixtures of less complexity than the naturally-

[1] Such compositions would include, for example, less complex compositions derived from naturally-occurring mixtures by fractionation, extraction, and other processing steps.

occurring mixture from which ethyl 3-mercaptobutyrate was originally identified.

Granted, the purified ethyl 3-mercaptobutyrate described in the application is "not a part of a naturally occurring mixture of compounds." However, what Appellants invented is a "purified" compound that, when introduced into a foodstuff, imparts a unique flavor to it. The only disclosure with respect to naturally occurring mixtures is that the concentration of ethyl 3-mercaptobutyrate is too low for it to be isolated from mango (Spec. 6: 10-12). As a consequence, ethyl 3-mercaptobutyrate was chemically synthesized – the form which is characterized in the Specification as "purified." In sum, we agree with the Examiner that claim 7 lacks a written description in the application.

Our decision is consistent with *In re Johnson and Farnham*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977), a CCPA case which dealt with exclusionary language in a claim that was not present in the application upon which priority was based. In *Johnson*, the applicant was attempting to narrow the scope of a claimed genus of compounds by excluding two species which had been lost in an interference. The Examiner, in a rejection affirmed by the Board of Appeals, asserted that the claims were not entitled to the 1963 filing date of the application because the claimed subject matter was not described in it as required by 35 U.S.C. § 112, first paragraph. The CCPA reversed. "The only inquiry is whether, after exclusion from the original claims of two species specifically disclosed in the 1963 application, the 1963 disclosure satisfies § 112, first paragraph, for the 'limited' genus now claimed." *Johnson*, 558 F.2d at 1017-1018, 194 USPQ at 195.

The CCPA found that it did because its priority application contained "a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed." *Johnson*, 558 F.2d at 1018, 194 USPQ at 196.

The CCPA distinguished an earlier case, Welstead, in which an applicant sought to exclude subject matter from an originally claimed genus, because in that case the new subgenus was not described in the application nor was there a description of "[its] species thereof amounting in the aggregate to the same thing." *Johnson*, 558 F.2d at 1018, 194 USPQ at 196.

The CCPA concluded:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.

Johnson, 558 F.2d at 1019, 194 USPQ at 196.

In this case, there is no description in the Specification – as there was in *Johnson* – of a genus minus what has been excluded from the claim. The Specification describes only one species – purified ethyl 3-mercaptobutyrate – and no other. There is no detailed description to show that Appellants possessed the invention which is now claimed.

Appellants argue that "[i]t has always been clear that appellant merely wishes to claim ethyl 3-mercaptobutyrate in purified form as an organoleptic agent and not ethyl 3-mercaptobutyrate in a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same

as the naturally occurring mixture of compounds" (Br. 11). However, purified claim ethyl 3-mercaptobutyrate is not what is presently claimed.

Thus, we conclude that the phrase "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or a part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds" is new matter to the Specification in violation of the written description requirement of 35 U.S.C. § 112, first paragraph. The rejection of claims 7-12 is affirmed.

Indefiniteness rejection under § 112, second paragraph

There are three rejections at issue in this appeal for lack of definiteness under 35 U.S.C. § 112, second paragraph. First, claims 7-12 stand rejected as indefinite because "it is unclear exactly what constitutes, in the context of the invention, 'a naturally occurring mixture of compounds.'" (Answer 7.) Related to this issue, the Examiner states that if the claims are interpreted to exclude any mixture of naturally occurring compounds, "the compositions specified in claims 10-12 lack antecedent basis" because they would exclude Appellants' "most preferred embodiments: the beverage, confection and chewing gum" (Answer 9-10). Third, the Examiner states that claim 7 is indefinite "[b]ecause a naturally occurring mixture and a synthetic mixture are *not* the same, they cannot as a matter of fact properly be characterized as such" (Answer 13).

We reverse the rejections. The phrase "naturally occurring mixture of compounds," when properly interpreted, means a "mixture of compounds" that can be found in nature (see *supra* at p. 3-4). This is not indefinite nor does it lead claims 10-12 to lack antecedent basis.

The characterization of the synthetic mixture as being the "same" as the naturally occurring mixture would be understood by persons of skill in the art to mean that the profile of compounds in the mixtures are the same. Thus, we do not find that this term introduced ambiguity into the claim.

Anticipation by Nielsen

Claims 7-9 stand rejected under 35 U.S.C. § 102 as anticipated by Nielsen.

Nielsen describes the synthesis of ethyl 3-mercaptobutyrate (Nielsen, at 408; Answer 11). The ethyl 3-mercaptobutyrate accumulates in a hexane phase in the reaction vessel (Nielson, at 408; Answer 11). The Examiner contends that "[s]ince hexane is an ingestible vehicle, in the broadest reasonable interpretation of the term, when considered in light of the instant specification, the Nielsen . . . reference is anticipatory. Hexane is capable of being ingested, thus it is an ingestible material" (Answer 11).

Appellants contend that hexane is not an "ingestible vehicle" as would be understood in the light of the Specification (Br. 7-8). "As set out in appellant's specification, 'ingestible' means to take in as food. Appellant's specification states that '[a]pplicant has discovered that ethyl 3-mercaptobutyrate . . . possesses unexpected flavor properties and imparts a unique note to flavors, *especially for conferring in foodstuffs* . . .' Appellant's specification at page 5, lines 27-31. (emphasis added)" (Br. 8). Appellants provide evidence that hexane is "a toxic substance causing central nervous system effects including dizziness, giddiness, nausea, and headache" and therefore not ingestible as a food (Br. 7-8).

In our opinion, Appellants have the better argument. Claim terms are given their broadest reasonable interpretation as they would be understood by persons of ordinary skill in the art when read in the context of the Specification. We have interpreted "ingestible" to mean a material that can be present in a food (see *supra* at p. 4) because the Specification describes the invention as purified ethyl 3-mercaptobutyrate as a flavoring to be used in foodstuffs (Spec. 5: 33-38). The Examiner's interpretation of "ingestible vehicle" is broad, but not *reasonable* in light of the Specification's teaching about the use of ethyl 3-mercaptobutyrate in food.

Appellants have introduced evidence, unrebutted by the Examiner, that hexane is a toxic substance and therefore would not be considered an "ingestible vehicle" as required by claim 7. We find this evidence persuasive, and thus concur with Appellants that the Examiner erred in rejecting claims 7-9 as anticipated by Nielsen. We reverse this rejection.

Anticipation by Lazier

Claim 7 stands rejected under 35 U.S.C. § 102(b) as anticipated by Lazier.

Lazier teaches the synthesis of ethyl 3-mercaptobutyrate having 87% purity (Lazier, at col. 3, ll. 35-37; Answer 12). The Examiner contends that this composition meets the limitation of claim 7 requiring the presence of an ingestible vehicle "because there is some additional material contained besides the mercapto-ester compound (the 'ingestible vehicle')" (Answer 12).

Appellants contend that "[t]he Examiner may NOT assume that this additional material (13%) is an ingestible material. Lazier et al. does not

identify this additional material. This additional material could just as readily be one or more toxic (non-food) substances. Lazier et al. was not seeking to make flavoring agents for use in ingestible vehicles but rather was seeking to make starting materials for use in polymers (Lazier et al. at col. 1, lines 4-9). Hence, Lazier et al. was not concerned whether this additional material (13%) was an ingestible material" (Br. 10).

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003) (internal citations omitted). *See* also *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F3d 1331, 1343 74 USPQ2d 1398, 1406 (Fed. Cir. 2005). "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The issue raised by this rejection is whether the Examiner has provided a reasonable basis for shifting the burden to Appellants to establish that the claimed composition is distinguishable from Lazier's composition; and if so, whether Appellants' burden has been met. In our opinion, the Examiner met his burden, but Appellants did not.

Lazier's Example II, relied upon by the Examiner for its disclosure of a fraction that "analyzes for 87% purity as ethyl 3-mercaptobutyrate" (Lazier, at col. 3, ll. 36-38), also comprises "[w]ater . . . formed in the course

of the reaction" (Lazier, at col. 3, ll. 38-39). Since water is an ingestible vehicle, we conclude that its presence is enough to provide reasonable basis for considering Lazier's composition to be the same as the composition of claim 7. Appellants had the opportunity to provide evidence that Lazier's synthetic method would not result in an ingestible composition as required by claim 7, but no evidence was offered in rebuttal. Accordingly, we affirm the rejection.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Ssc

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